

IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION

MADENNA K. DORGAN, AND; AND)
RICHARD DORGAN,)
)
Plaintiffs,)
) Case No. 4:20-00529-CV-RK
v.)
)
ETHICON, INC.; AND JOHNSON &)
JOHNSON)
)
Defendants.)

**ORDER DENYING MOTION TO LIMIT THE CASE-SPECIFIC OPINIONS AND
TESTIMONY OF BRUCE ROSENZWEIG, M.D.**

Before the Court is Defendants' motion to exclude the case-specific opinions and testimony of Bruce Rosenzweig, M.D. (Doc. 88.) The motion is briefed. (Docs. 89, 94.) After careful consideration, the motion is **DENIED**.

Background

This case arises out of the implantation and complications surrounding transvaginal mesh ("TVT") in Plaintiff Madenna Dorgan ("Ms. Dorgan"). On August 7, 2008, Ms. Dorgan underwent implantation of TVT, for treatment of stress urinary incontinence, performed by Dr. George Austin in Blue Springs, Missouri. On March 22, 2011, Dr. Austin removed a portion of extruded and exposed TVT from Ms. Dorgan. On October 23, 2012, Ms. Dorgan underwent surgery for mesh removal performed by Dr. Ebenezer Babalola in Kansas City, Kansas. On April 3, 2013, Ms. Dorgan underwent another mesh-removal procedure performed by Dr. William Wilson in Blue Springs, Missouri. Plaintiff alleges that her TVT implant has caused her several injuries, including the following: severe pain; permanent vaginal-wall damage; nerve damage; vaginal scarring; erosion; incontinence; dyspareunia; inflammation; and urinary tract infections. Plaintiff has retained Dr. Rosenzweig to provide expert testimony as to the design of the TVT, the sufficiency of Defendants' warnings and disclosures, that there were reasonably safer alternatives, and that the TVT used caused Ms. Dorgan's injuries.

Legal Standard

Federal Rule of Evidence 702, amended after *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), provides the standard for the admission of expert testimony:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Based on Rule 702, the Eighth Circuit gives a three-part test to determine the admissibility of expert testimony:

First, evidence based on scientific, technical, or other specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. This is the basic rule of relevancy. Second, the proposed witness must be qualified to assist the finder of fact. Third, the proposed evidence must be reliable or trustworthy in an evidentiary sense, so that, if the finder of fact accepts it as true, it provides the assistance the finder of fact requires.

Lauzon v. Senco Prod. Inc., 270 F.3d 681, 686 (8th Cir. 2001) (internal quotations and citations omitted). The rules for the admissibility of expert testimony favor admission over exclusion. *Id.* These rules are also relaxed during bench trials. *David E. Watson, P.C. v. United States*, 668 F.3d 1008, 1015 (8th Cir. 2012). If an expert makes observations and applies specialized knowledge to include and exclude theories of causation, then their conclusions are generally admissible as expert opinion. *Shuck v. CNH Am., LLC*, 498 F.3d 868, 875 (8th Cir. 2007) (holding that the opinions and testimony of fire causation experts were admissible when those experts observed a combine engine and applied their specialized knowledge to determine the cause of the fire).

Discussion

Defendants now move to exclude several of Dr. Rosenzweig's opinions. The court will address each challenged opinion in turn.

I. Dr. Rosenzweig does not Opine as to Defendants' State of Mind or Corporate Knowledge

First, Defendants seek to exclude testimony and opinion from Dr. Rosenzweig as to Defendants' state of mind, knowledge, or conduct. Defendants specifically object to the opinion stating Ethicon failed to inform Ms. Dorgan's implanting surgeon of risks "despite information readily available to Ethicon about these risks." (Doc. 88-1, p. 14.) Defendants' argument is without merit.

Dr. Rosenzweig formulated his opinion based on the facts and evidence of the case. (See *Id.*) From the facts, Dr. Rosenzweig knows, at least generally, of the information available to Defendants concerning the risks of TTV and the warnings given to providers and the public. Dr. Rosenzweig's opinions then do not go to the state of mind of the Defendants, but rather are based on the objective facts of the case. Finally, the opinions attacked in this point are of general causation. The MDL court previously denied motions brought on that basis, and this Court will as well. *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-CV-03074, 2017 WL 2214895, at *2 (S.D. W. Va. May 18, 2017) ("I will not rule on general causation issues raised in a specific causation motion. Accordingly, Ethicon's Motion on this point is **DENIED.**") (emphasis in original). Therefore, Defendants' motion will be denied on this point.

II. Dr. Rosenzweig's Opinions Regarding the Adequacy of Warnings are Admissible

Defendants then argue Dr. Rosenzweig is not qualified to testify as to the adequacy of the warnings in this case and that the adequacy of warnings could not be a proximate cause, making the opinions irrelevant. Defendants' arguments are again without merit. At least one other court has already found Dr. Rosenzweig qualified to testify on these issues. *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 704 (S.D.W. Va. 2014) ("I therefore **FIND** that Dr. Rosenzweig is qualified to testify generally on the adequacy of the TTV-O's product warnings and marketing materials.") (emphasis original). This Court too finds Dr. Rosenzweig qualified to testify on these issues. To any extent Defendants believe Dr. Rosenzweig to be unqualified, they can cross-examine him. As to the argument regarding proximate cause, Defendants offer nothing more than a conclusory assertion. Such an assertion, that inadequate warnings are not the proximate cause, is insufficient to warrant limiting expert testimony. Defendants motion will be denied as to this point.

III. Dr. Rosenzweig's Opinions Regarding the Complications of TTV in Ms. Dorgan are Admissible

Next, Defendants argue Dr. Rosenzweig is not qualified to testify as to the complications of TTV in Ms. Dorgan and that these opinions are otherwise inadmissible. As to the qualifications argument, the Court has already rejected this argument above in Section II. As to the arguments that these opinions are not otherwise admissible, Defendants' arguments fail. Dr. Rosenzweig is a qualified expert, who has extensive knowledge and experience with transvaginal mesh and similar products, and based his opinions on the medical records and differential diagnosis. The Court finds persuasive that other courts have rejected similar arguments and have allowed

Dr. Rosenzweig to testify as an expert. *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 565 (S.D.W. Va. 2014), as amended (Oct. 29, 2014) (holding that “a physician may reach a reliable differential diagnosis without personally performing a physical examination” and allowing Dr. Rosenzweig to testify as to both general and specific causation.) Defendants’ motion will be denied on this point.

IV. Dr. Rosenzweig’s Opinions Regarding Safer Alternatives are Admissible

Additionally, Defendants argue Dr. Rosenzweig’s opinions regarding safer alternatives are not reliable and irrelevant. As to the relevance argument, whether a safer alternative exists and whether it would have reduced or eliminated the risk of injury goes to the heart of causation and damages. *See Newman v. Ford Motor Co.* (“a design is in a defective condition unreasonably dangerous if a reasonable, feasible, safer, alternative design would have reduced or prevented the plaintiff’s injuries, and if the omission from the product of that alternative rendered the product not reasonably safe.”).

As to reliability, Defendants argue there is no basis for Dr. Rosenzweig’s opinion that had Ms. Dorgan used alternative designs she would not have suffered her injuries. Dr. Rosenzweig’s opinion is based on his experience with the alternatives proposed in his report and his opinion that Ms. Dorgan’s injuries were caused by the specific design flaws of the TVT. (Doc. 88-1.) As Dr. Rosenzweig explains, every other alternative uses less or no polypropylene. (*Id.*) Finally, Dr. Rosenzweig states these opinions to a reasonable degree of medical certainty, not absolute certainty. *See United States v. Cottom*, No. 8:13CR108, 2015 WL 9308226, at *8 (D. Neb. Dec. 22, 2015), *aff’d*, 679 F. App’x 518 (8th Cir. 2017) (“scientific evidence need not be shown to a level of absolute certainty to be admissible.”). Merely because there may be a chance the injuries would occur using an alternative product does not warrant the full exclusion of the opinions. The Court finds the opinions here are sufficiently reliable and the Court will deny Defendants motion as to this point. To any extent Defendants disagree with said opinions, they can be taken up on cross-examination.

V. Dr. Rosenzweig’s Opinions on the Informed Consent Process are Admissible

Regarding the informed consent process, Defendants argue Dr. Rosenzweig’s opinions are a mere restatement of his inadequate warning opinions and venture into opining on Dr. Austin’s personal knowledge. Both arguments are without merit. First, while the opinions about the sufficiency of warnings are inherently intertwined to the issue of whether Ms. Dorgan could give informed consent, they remain two distinct issues. Plaintiffs must prove causation. In this case,

regarding warnings, Plaintiffs will have to prove that a sufficient warning(s) (either to the medical providers or patient), would have altered Ms. Dorgan’s behavior. In Missouri, plaintiffs are entitled to the presumption that, if an adequate warning had been given, they would have heeded it. *Winter v. Novartis Pharm. Corp.*, 739 F.3d 405, 408 (8th Cir. 2014) (quoting *Moore v. Ford Motor Co.*, 332 S.W.3d 749, 761-63 (Mo. 2011)). Such an issue touches on not only the adequacy of the warnings, but their effect on patient behavior via an informed consent process. Second, Dr. Rosenzweig will not testify to any of Dr. Austin’s personal knowledge. Rather, Dr. Rosenzweig opines as to the sufficiency of warnings given to surgeon’s like Dr. Austin and how the lack of warnings affected the informed consent process. Therefore, Defendants’ motion will be denied on this point.

VI. Dr. Rosenzweig’s Opinions Concerning Degradation, Rigidity, Fraying, Roping, Cording, and Curling are not Speculative and are Sufficiently Reliable

Finally, Defendants argue Dr. Rosenzweig’s opinions concerning any deformation, rigidity, fraying, roping, cording, and curling in Ms. Dorgan’s specific device(s) should be excluded as unreliable because Dr. Rosenzweig has not personally examined, analyzed, or tested Ms. Dorgan’s implant. Both Defendants and Plaintiffs cite to cases decided by Judge Goodwin in the Southern District of West Virginia. *Huskey*, 29 F. Supp. at 707-08 (finding Dr. Rosenzweig’s opinion on degradation, fraying, and particle loss not sufficiently reliable); *Tyree*, 54 F. Supp. 3d at 565 (allowing Dr. Rosenzweig’s opinions regarding specific causation related to shrinkage). This Court finds *Huskey* distinguishable. Whereas in *Huskey*, Dr. Rosenzweig did not attempt to rule out potential causes for tenderness, in *Tyree*, the court noted, “Dr. Rosenzweig thoroughly considered Ms. Blankenship’s medical history and test results in the light of the applicable publications.” *Huskey*, 29 F. Supp. at 708; *Tyree*, 54 F. Supp. 3d at 567. Here, Dr. Rosenzweig performed a differential diagnosis after a review of the medical records and ruled out other potential causes of Ms. Dorgan’s injuries. From this, the Court finds Dr. Rosenzweig’s opinions sufficiently reliable. Therefore, the Court will deny Defendants’ motion on this point.

Conclusion

The Court again notes that all of these opinions are subject to cross-examination, but they satisfy the *Daubert* standard. Accordingly, and after careful consideration, Defendants' motion to exclude certain opinions and testimony of Dr. Rosenzweig (Doc. 88) is **DENIED**.

IT IS SO ORDERED.

s/ Roseann A. Ketchmark

ROSEANN A. KETCHMARK, JUDGE
UNITED STATES DISTRICT COURT

DATED: September 8, 2020